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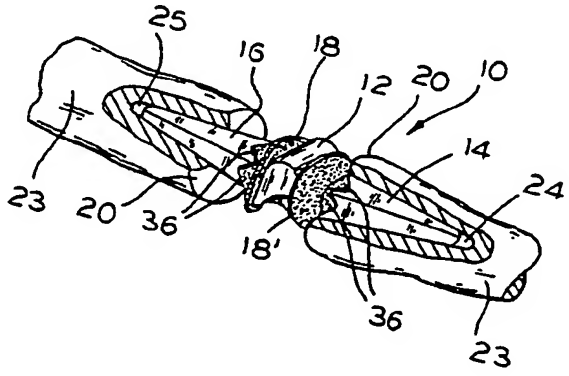

(57) Abstract

A protective device (18) for preventing damage to surgically implantable prostheses (12) from sharp, irregular bone edges of resected bone. The protective devices (10) are generally disc shape having substantially planar faces (27) wherein an aperture (30) is cut through the center of face (37) for permitting stem portions (14, 16) to be inserted therethrough to interface between the resected bone and the surface of the prostheses (12).

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Protective Device for Implantable Prosthesis

Background of the Invention

Rheumatoid arthritis is an inflammatory disease of the soft tissues that causes severe destruction of the joint tissues. Inter alia, the disease weakens the capsule and ligament of the joint, causing the fingers to become displaced. Prior to the advent of implant arthroplasty of these joints, resection arthroplasty and a procedure known as fusion were the only alternatives to either relieve pain and to restore functional range of motion to the affected areas. Resection arthroplasty merely removed the joint capsule which allowed the space to fill in with a new surface of fibrous tissue, providing a false joint. Fusion caused a bond union across the joint, provided stability and relief of pain, but did not allow for motion in the fused joint. Implant resection arthroplasty is a surgical procedure performed to correct finger-joint deformation in patients with severe destruction of joints caused by progressive rheumatoid arthritis. A flexible elastomeric implant, preferably of silicone rubber, is the most commonly used adjunct to this arthroplasty procedure. Examples of such prosthetic joints include those disclosed in U.S. Patent Nos.: 3,462,765; 3,593,342; 3,681,786; 3,818,513; 3,875,594; 3,879,767; 3,886,600; and 4,178,640.

One of the problems encountered with these flexible implants is crack propogation and susceptibility to stress which ultimately leads to joint implant failure. During the healing processes following bone resection, sharp jagged edges of bone may develop which eventually initiate tears and cracks in the elastomeric

implant. Swanson, in U.S. Patent Nos. 4,158,893 and 4,198,713, has disclosed various protective devices for preventing lacerations or tearing of these flexible implants due to the damaging effects of the spur bone formation of the resected bone. In U.S. Patent No. 4,158,893 the protective device is a sleeve adapted to fit within the intramedullary canal, wherein the sleeve is made of medical grade material such as porous polytetrafluoroethylene or high density polyethylene, which permits the bone to grow into its exterior surface. In U.S. Patent No. 4,198,713, the protective device is a curvilinear shield adapted to conform to the upper portion of the prosthesis outer surface, wherein the shield is made of highly polished stainless steel which permits relative sliding, reciprocating motion between the prosthesis and the protective device.

While these various devices described hereinabove would provide a protection to the implant from tears produced by spurious bone formation on the resected bone surface, they have suffered from bone resorption at the interface and cracking of the protective device. A need therefore exists for a device which interfaces between the flexible implants and the resected bone which not only discourages or inhibits the formation of bone spurs and sharp irregular bone, but promotes a smooth, regular, even remodeling of the resected bone surface and thus provides a smooth edge at this interface. Heretofore, no such device has been available.

Summary of the Invention

In accordance with the present invention, disclosed is a device for protecting surgically implantable prostheses used to repair resected bone or to replace bone joints, wherein the prosthesis has a body portion and at least one outwardly-directed stem portion, and the protective device is a piece of fixed, soft biological tissue having a means therein for passage of the prosthesis stem portion, and having overall dimensions sufficient to cover at

least a portion of the outer surface of the prosthesis body portion adjacent the stem portion such that a prosthesis-to-bone interface is provided between at least a portion of the exposed resected bone and a portion of the prosthesis when the prosthesis is implanted.

Description of the Drawings

FIG. 1 is a cross-section of the human hand showing the protective device in accordance with one embodiment of the present invention;

FIG. 2 is an enlarged perspective view of the device shown in FIG. 1, having the bone partially sectioned to show the intramedullary canals;

FIG. 3 is an exploded front elevational view of a surgical implantable prosthesis used to replace bone joints and the protective device of the present invention;

FIG. 4 is a perspective view of the proximal protective device in accordance with one embodiment of the present invention;

FIG. 5 is a perspective view of the distal protective device in accordance with one embodiment of the present invention;

FIG. 6 is an elevational view of an alternate protective device in accordance with the present invention;

FIG. 7 is an elevational view of an alternate embodiment of the present invention;

FIG. 8 is an elevational view of an alternate protective device of the present invention having a portion for extending into the intramedullary canals.

Detailed Description of the Preferred Embodiment

In accordance with the present invention, disclosed is a protective device for surgically implantable prostheses used to repair resected bone or to replace bone joints. By way of example, the prosthesis may be of the type used for finger, toe, wrist, trapezium, carpal scaphoid, carpal lunate, and radial head implants, and may be a flexible elastomeric joint implant as described in U.S. Patent Nos. 4,198,713; 4,158,893; 3,875,594; 3,462,765; 3,593,342; 3,681,786; 3,818,513; 3,879,767; 3,886,600; 4,178,640 which are hereby incorporated by reference into this application. Alternatively, the prosthesis may be of the type used in bone amputation, or any other bodily area where resected bone may grow in a jagged, irregular way, in the form of sharp edges that can cut the elastomeric surfaces of the prosthesis.

For the purpose of illustration, an implantable finger joint prosthesis is generally shown at 10 in FIGS. 1.3. The prosthesis is ordinarily made of flexible elastomeric material such as silicone rubber and sold under the trademark Silastic by Dow Corning Corporation, Midland, Michigan. The prosthesis comprises a hinge-like flexible body portion 12 having a substantially rigid distal stem portion 14 directed outwardly from the body portion, and an outwardly- directed proximal stem portion 16 extending in a direction subs- tantially opposite from that of the distal stem portion. It is to be understood that the stem portions 14 and 16 may project outwardly from the central body portion 12 at various angles depending on the exact configuration required to adapt the prosthesis to various implant sites. Alternatively, the prosthesis may comprise a body portion 13 having a single stem portion 15 extending outwardly therefrom for insertion into the ends of amputated bones as show in FIG. 7.

The protective device in accordance with one embodiment of the present invention is shown at 18 and 18' as a generally oval web conforming to the major portion of the prosthesis body surface

12 that comes in contact with the resected bone surface 20 when fully implanted. As further described hereinbelow, the protective device is preferably constructed of fixed, soft biological tissue having overall dimensions sufficient to cover at least a portion of the outer surface 22 of the prosthesis body portion adjacent the stem portion 14, 15, or 16 such that a prosthesis-to-bone interface is provided between at least a portion of the prosthesis when the prosthesis is inserted into the intramedullary canal.

In accordance with the present invention, the protective device may be used in conjunction with any intermedullary stemmed flexible prosthetic implant where a resected bone-implant interface occurs. In particular, these areas include wrist, toe, and the finger implants shown in FIG. 1. During a typical implantation procedure, the normal joint of a bone 23 is partially, surgically severed or resected leaving an exposed bone surface 20; and the intramedullary canals 24 and 25 are bored to receive the stem portions 14 and 16 of the prosthesis 10. After insertion of the implant, sharp, jagged edges of bone normally develop particulary at the resected bone surface 20 which eventually initiate a crack in the flexible implant. In accordance with one embodiment of the present invention, the protective device 18 and 18' is interposed between the exposed resected bone surface and the prosthetic implant 10 and acts as a barrier or interface therebetween to promote relatively smooth remodeling or reshaping of the bone surface into a regular edge and shield the implant from sharp bone spurs.

In accordance with the present invention, the protective device 18 and 18' is generally disc-shaped as generally shown at 26 in FIGS. 4 and 5. In accordance with one embodiment of the present invention, the external dimensions of the said tissue are sufficient to cover substantially the entire outer surface 22 of the prosthesis body portion 12 adjacent the stem portion such that a prosthesis-to-bone interface is provided between substantially all of the resected bone surface 20 and the body portion 22 of the

prosthesis when the implant is inserted into the intramedullary canal 24 and 25. Thus, it will be understood that the external dimensions of the tissue 26 will be dependent upon the size of the prosthesis which, in turn, is dependent upon the type of joint replacement and site at which the joint is replaced.

A web in accordance with one the present invention, is a piece of shaped biological tissue having generally planar faces 27 defining an area which has lateral dimensions relatively larger than the thickness of the tissue.

In a preferred embodiment of the present invention, the external dimensions of said tissue are sufficient to cover at least a portion of the stem portion adjacent the prosthetic body portion in addition to covering the body portion as described above and at 38 such that a prosthesis-to-bone interface is additionaly provided between a portion of the exposed resected bone in the intramedullary canal and a portion of the stem portion.

In accordance with one embodiment of the present invention, the protective device is of biological tissue cut in a generally rectilinear shape 28 as shown in FIG. 6 having a major axis (f) of from about 0.31 to about 0.73 inches and a minor axis (g) of from about 0.16 to about 0.53 inches. An aperture 30 is cut through the center of the face 27 of the tissue for passage of the prosthesis stem portion. The aperture has a major axis (h) of from about 0.13 to about 0.39 inches, and a minor axis (i) of from 0.12 to about 0.27 inches.

In a preferred embodiment of the present invention, the biological tissue is cut in a generally oval shape as shown in FIGS. 4 and 5. The proximal device 18 depicted in FIG. 4 has a major axis (a) of from about 0.32 to about 0.73 inches, and a minor axis (b) of from about 0.16 to about 0.53 inches. The tissue, which is approximately 0.016 inches in depth (e), has a pair of intersecting slits 32 and 32' cut through its face 27 for

providing passage of prosthesis stem portion. The intersecting slits are generally X-shaped, and describe an area from end-to-end having lateral dimensions (c) of from about 0.10 to about 0.29 inches and (d) of from about 0.10 to about 0.29 inches.

The distal device 18' depicted in FIG. 5 is generally similar to the proximal web 18; however, it has a truncated side portion 34. The tissue has a major axis (a') of from 0.32 to about 0.73 inches, a minor axis (b') of from 0.15 to about 0.52 inches, and intersecting slits 32 and 32' describing an area from end-to-end having lateral dimensions of (c') from about 0.10 to about 0.29 inches, and (d') from about 0.08 to about 0.25 inches, and a thickness (e') of approximately 0.016 inches.

In accordance with the present invention, the biological tissue is either naturally occurring biological tissue derived from various animal sources including but not limited to bovine, porcine, horse, sheep, kangaroo, or rabbit; and can be obtained from various parts of the anatomy as described hereinbelow. Alternatively, the biological tissue can be composed of collagen or reconstituted collagen substitutes including but not limited to collagen-fabric films, collagen-membranes, reconstituted collagen on Dacron mesh, tanned collage sponge grafts and the like. In accordance with the present invention, the soft biological tissue provides a moist lubricious, flexible interface between the bone and implant; and also promotes the even, remodeling of resected bone resulting in a smooth bone surface. Moreover, the biological tissue is stable when implanted into the body. It is well understood that soft biological tissue differs from hard biological tissue found in bone, teeth, and the like.

In accordance with the present invention, naturally occurring biological tissue is removed from its host, defatted if necessary and processed in one of several well-known procedures used to prepare the tissue for implantation into humans. The tissue is fixed (tanned) conventionally in from about 0.2 to about 0.6

weight percent glutaraldehyde in either phosphate-buffered solutions, or phosphate-free buffers as described in the copending U.S. patent application Serial No. 445,345 filed on November 29, 1982. The tissue handling conditions as conventionally known are not considered part of the present invention unless otherwise stated. Likewise, tissue may be sterilized in about 0.625 percent glutaraldehyde or from about 4 to about 5 percent formaldehyde.

Naturally occurring biological tissue in accordance with the present invention includes, but is not limited to epithelial and fibrous connective tissue such as pericardial tissue, dura mater, facialata, amnion, tendon, ligament, cartilage, and the like. The epithelial tissues such as dura mater, amnion, facialata, and percardium generally comprise two layers each; a fibrious, proteinaceous layer and a relatively smooth membranous layer. In accordance with one embodiment of the present invention, the rough, fibrous layer of the tissue is placed against the resected bone to provide better anchoring to the bone surface, while the smooth, membranous layer is positioned to contact the prosthesis surface and provide a more lubricious interface. In accordance with the present invention, pericardial tissue is preferred.

In accordance with a preferred embodiment of the present invention, the natural biological tissue is treated prior to implantation to render it substantially resistant to calcification. This advantageously maintains the biological tissue in a more flexible state than calcified tissue, allowing the tissue to conform better to the uneven surface of the resected bone. Calcification mitigation treatments of biological tissue are not considered part of the invention but can be found in copending U.S. patent applications Serial Nos. 445,345 filed November 29, 1982; 377,747 filed May 13, 1982; and 441,023 filed November 12, 1982; and in U.S. Patent No. 4,323,358.

In accordance with the present invention, the protective device 18 and 18' is intended to minimize the potential for

prosthetic implant fracture by acting as a spacer between the joint implant 10 and the resected bone surface 20. Studies conducted in rabbits, as described hereinafter, show that when the protective device 18 and 18' is placed in contact with resected bone, the bone healing process results in a smooth bone surface with minimal inflammation and no necrosis.

Animal Studies

The rabbit knee was used as the experimental model because the size of the rabbit's knee joint is comparable in size to that of the human finger joint. The animal study consisted of two groups. The control group animals received the prosthetic implant without the protective device, and the experimental group received the prosthetic implant with the protective device. After six and twelve weeks, the implants were retrieved from the rabbits and examined for wear and cellular activity. Histology was performed on the bone protective device interface and on the capsule surrounding the joint space to determine host cellular reaction to the protective device and the implant.

The histological evaluation of 36 silicone joint implants retrieved from 36 rabbits indicates that the presence of biological tissue interposed between the implant and resected bone surface in accordance with the present invention significantly reduced wear of the silicone implant, indicating that the implant will function longer without fracturing when implanted into humans.

The silicone joint implant showed pathological evidence of wear debris as is common in many prosthetic materials. The amount of silicone debris was not only related to the length of time the implant was in place, but more importantly to stress factors. The most important factors appeared to be related to sharp bone edges at the ostial opening and to fibro-osseous "humps" which formed in the surgical channel in which the prosthesis was placed. Abrasions and gouges were most prominent on the tibial side of the

implant, particularly in the control animals. The silicone debris resulted in predominantly a mononuclear histiocyte response and a mild to moderate multinucleate histiocyte response, generally mild to moderate chronic inflammation and eventually fibrosis, most always in direct proportion to the amount of debris. The control animals showed significantly greater amounts of silicone debris than did the experimental animals, which would be expected when the device minimizes wear.

The biological tissue, when it covered the ostial surface, the entrance edge of bone, and the upper channel into the bone significantly reduced silicone wear. The tissue caused little histiocytic reaction or chronic inflammation.
There was no acute inflammation or necrosis caused by either the tissue or the silicone debris in any experimental time period even as early as two weeks. In one case, the tissue was being bound down on its lateral deep edges by living rabbit fibroblasts and incorporated as Sharpey's-like fibers into rabbit cartilage with no adverse tissue reaction.

The following table shows the comparison of the implants in the control animals with those using biological tissue as a protective device.

Table 1

% of animals

Observation	Control (n=7)	With Biological Tissue (n=10)
Moderate wear and cracking to completely fractured implant and/or deformation implant failure)	43%	10%
Slight wear, scratching and/or deformation normal wear)	43%	20%
Minimal or no signs of wear, no distinct lacerations of the implant surface normal wear)	14%	70%

The protective device 18 and 18', in accordance with the present invention, can be placed around the stem portion 14 and 16 of a surgically implantable prosthesis 10 and sold in a fully assembled manner, or they may be packaged in a sterile sealed package (jar) separately from a prosthesis such that the physician or surgeon can place the device on the prosthesis just prior to implantation. Preferably, and by way of example, a distal 18' and proximal 18 device may be contained in a sterile package. Prior to insertion of the implant into the intramedullary canal 24 and 23 of the resected joint bone, the webs are placed on the stems 14 and 16 of the implant with the smooth side of the tissue facing the body portion of the prosthesis. The fibrous, textured side is directed away from the prosthesis and toward the surface of the resected bone. The distal web is placed on the distal stem of the prosthesis with the truncated 34 edge facing toward the palmar

surface. Preferably the web has a pair of slits 32 and 32' in its face 27 that form flaps 36 to cover a portion of the stem adjacent the body of the prosthesis. These flaps 36 preferably fit snugly and squarely around the stem of the prosthesis. Once the proximal stem of the prosthesis is in the intramedullary canal of the metacarpal, the implant is flexed so tht the distal stem can easly be inserted into the proximal phalanx with the flaps carefully tucked into the bone canal. With the joint in extension, there should be no impingement of the implant; and the webs should preferably be flat against the midsection of the implant and not restrict its movement or function.

The present invention has been described in specific detail and in reference to its preferred embodiments; however, it is to be understood by those skilled in the art that modifications and changes can be made thereto without departing from the spirit and scope thereof.

I claim:

1. A protective device for a surgically implantable prosthesis used to repair resected bone or to replace bone joints, the prosthesis having a body portion and at least one outwardly-directed stem portion; said protective device comprising:

a piece of fixed, soft biological tissue having a means therein for passage of the prosthesis stem portion, and having overall dimensions sufficient to cover at least a portion of the outer surface of the prosthesis body portion adjacent the stem portion such that a prosthesis-to-bone interface is provided between at least a portion of the exposed resected bone and a portion of the prosthesis when the prosthesis is implanted.

2. The device of Claim 1 wherein the protective device is of soft, naturally occurring biological tissue fixed with glutaraldehyde.

3. The device of Claim 2 wherein the biological tissue is epithelial or fibrous connective tissue.

4. The device of Claim 2 wherein the biological tissue is selected from the group consisting of pericardial tissue, dura mater, fascialata, or amnion.

5. The device of Claim 2 wherein the biological tissue is tendon or ligament.

6. The device of Claim 2, 3, 4, or 5 wherein the biological tissue is substantially resistant to calcification.

7. The device of Claim 6 wherein the piece of biological tissue is generally rectilinear.

8. The device of Claim 7 wherein the passage means is an aperture through the face of the tissue.

9. The device of Claim 7 wherein the passage means is a pair of intersecting slits cut through the face of the tissue.

10. The device of Claim 6 wherein the piece of biological tissue is generally circular or oval.

11. The device of Claim 10 wherein the passage means is an aperture through the face of the tissue.

12. The device of Claim 10 wherein the passage means is a pair of intersecting slits cut through the face of the tissue.

13. The device of Claim 1 wherein the external dimensions of said tissue are sufficient to cover substantially the entire outer surface of the prosthesis body portion adjacent the stem portion such that a prosthesis-to-bone interface is provided between substantially all of the exposed resected bone surface and the body portion of the prosthesis.

14. The device of Claim 6 wherein the external dimensions of said tissue are sufficient to cover substantially the entire outer surface of the prosthesis body portion adjacent the stem portion such that a prosthesis-to-bone interface is provided between substantially all of the exposed resected bone surface and the body portion of the prosthesis.

15. The device of Claim 13 wherein the external dimensions of said tissue are sufficient to cover at least a portion of the stem portion adjacent the prosthetic body portion such that a prosthesis-to-bone interface is additionally provided between a portion of the exposed resected bone in the intramedullary canal and a portion of the stem portion.

16. The device of Claim 14 wherein the external dimensions of said tissue are sufficient to cover at least a portion of the stem portion adjacent the prosthetic body portion such that a prosthesis-to-bone interface is additionally provided between a portion of the exposed resected bone in the intramedullary canal and a portion of the stem portion.

17. A protective device for a surgically implantable flexible bone joint prosthesis said prosthesis having a body portion and at least one outwardly-directed stem portion adapted to be inserted in the intramedullary canal of resected bone; said protective device comprising:

a flexible piece of soft, glutaraldehyde-fixed natural biological tissue having a means in the face thereof for passage of the prosthesis stem portion, wherein said soft tissue is substantially resistant to calcification; and

said tissue further having overall dimensions sufficient to cover the outer surface of the prosthesis body portion adjacent the stem portion such that a prosthesis-to-bone interface is provided between the exposed resected bone surface, and the prosthesis body portion when the prosthesis is inserted into the intramedullary canal.

18. The device of Claim 17 wherein the biological tissue is epithelial or fibrous connective tissue.

19. The device of Claim 17 wherein the biological tissue is selected from the group consisting of pericardial tissue, dura mater, fascialata, or amnion.

20. The device of Claim 17 wherein the biological tissue is tendon or ligament.

21. The device of Claim 14 wherein the biological tissue is percardial tissue.

22. The device of Claim 17 wherein the passage means is an aperture through the face of the tissue.

23. The protective device of Claim 21 wherein the passage means is a pair of intersecting slits cut through the center face of the tissue.

24. A method of protecting a flexible implantable prosthesis used to replace bone joints or repair resected bone from damage caused by contact with irregular bone edges of the resected bone, wherein said method comprises placing fixed, soft biological tissue over at least a portion of the outer surface of said prosthesis prior to implanting said prosthesis such that a prosthesis-to-bone interface is provided between at least a portion of the resected bone and a portion of the prosthesis when the prosthesis is implanted.

25. The method of Claim 24 wherein the external dimensions of said tissue are sufficient to cover substantially the entire outer surface of the prosthesis body portion adjacent the stem portion such that a prosthesis-to-bone interface is provided between substantially all of the exposed resected bone surface and the body portion of the prosthesis.

26. The method of Claim 25 wherein the external dimensions of said tissue are sufficient to cover at least a portion of the stem portion adjacent the prosthetic body portion such that a prosthesis-to-bone interface is additionally provided between a portion of the exposed resected bone in the intramedullary canal and a portion of the stem portion.

27. The method of Claim 24, 25, or 26 wherein the fixed biological tissue is epithelial tissue, having a relatively smooth

surface and a fibrous surface, wherein the method further comprises interposing the tissue such that the filbrous surface contracts the resected bone and the smooth surface contacts the prosthesis.

28. A surgical implant kit having component parts capable of being assembled in the operating theatre for repairing resected bone or replacing bone joints, wherein said bone joints are in close proximity to resected bone; the kit comprising the combination of:

a prosthesis having a body portion and at least one outwardly-directed stem portion adapted to be affixed to the resected bone or bone joint; and

a piece of fixed, soft biological tissue adapted to interface between at least a portion of said prosthesis and at least a portion of said resected bone when the prosthesis is implanted;

whereby said tissue provides a protective barrier to said implant from irregular edges of said resected bone.

29. The kit of Claim 19 wherein the prosthesis has two stem portions extending outwardly from the body portion and in substantially opposite directions; and said kit further comprises a piece of tissue for each stem portion.

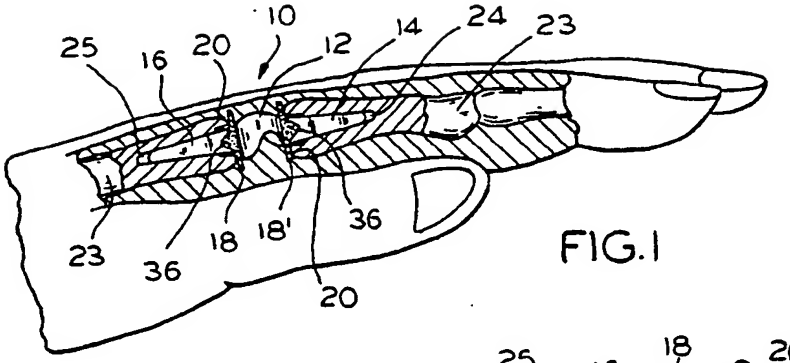

FIG.1

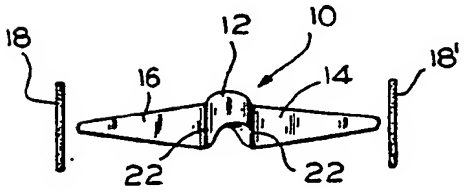

FIG.3

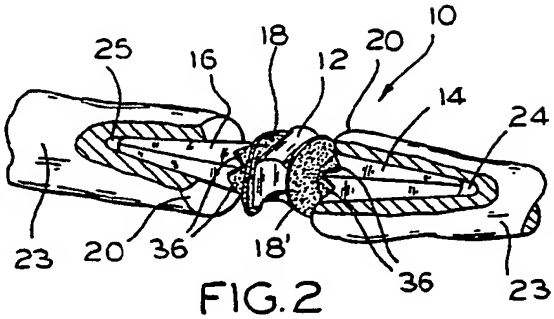

FIG.2

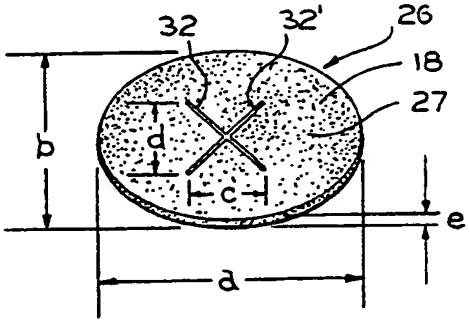

FIG.4

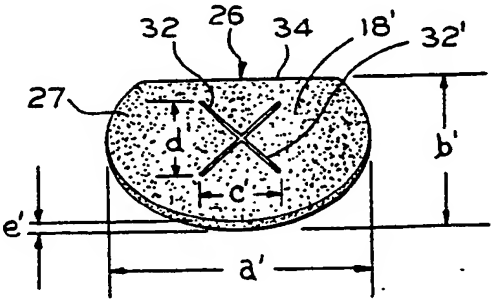

FIG.5

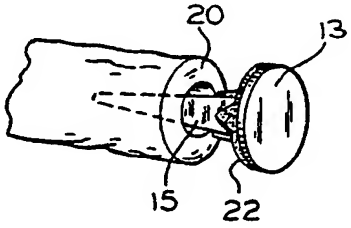

FIG.7

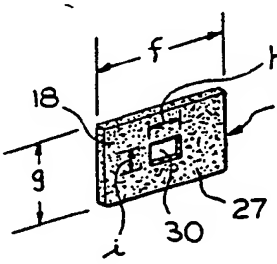

FIG.6

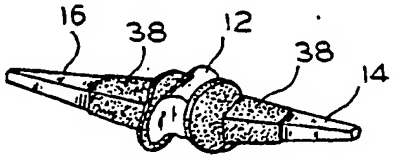

FIG.8

INTERNATIONAL SEARCH REPORT

International Application No PCT/US84/00769

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC: [3] A61F-1/00; 1/04; 5/04

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
US	3/1, 1.9, 1.91, 1.911, 1-512, 1.913 128/92C, 92CA, 92G, 1

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]		Relevant to Claim No. [18]
X, Y	US, A, 4,158,893	26 June 1979 SWANSON	1-5, 7-13, 15, 24-29
Y, P	US, A, 4,400,833	30 August 1983 KURLAND	1-5, 7-13, 15, 24-29
Y, P	US, A, 4,402,697	06 September 1983 POLLOCK et al	6, 14, 16-23

* Special categories of cited documents: [15]

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]: 8/8/84

Date of Mailing of this International Search Report [2]: 10 AUG 1984

International Searching Authority [1]: ISA/US

Signature of Authorized Officer [20]: D J Isabelle

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